

EXHIBIT CC

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1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 - - -
5 IN RE: ETHICON, INC. PELVIC :MDL NO. 2327
6 REPAIR SYSTEM, PRODUCTS :
7 LIABILITY LITIGATION :VOLUME II
8 :
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11 THIS DOCUMENT RELATES TO ALL CASES AND
12 VARIOUS OTHER CROSS-NOTICED ACTIONS
13 CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

14 - - -
15 January 8, 2014
16 - - -
17 Transcript of the continued deposition of
18 THOMAS A. BARBOLT, Ph.D., called for Videotaped
19 Examination in the above-captioned matter, said
20 deposition taken pursuant to Superior Court Rules of
21 Practice and Procedure by and before Michelle L.
22 Gray, a Certified Court Reporter, Registered
23 Professional Reporter, and Notary Public, at the
24 offices of Riker Danzig Scherer Hyland & Perretti
25 LLP, Headquarters Plaza, One Speedwell Avenue,
 Morristown, New Jersey, commencing at 9:07 a.m.

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1 the '97 time frame or so, and then I think the
2 510(k) approval was in early 1998.

3 Q. And the information that you list in
4 response to the degradation designation begins in
5 1964; is that right?

6 A. Yes, that's correct.

7 Q. And it runs in chronological order
8 all the way up until 2007, right?

9 A. Yes, that's correct.

10 Q. Why did you include studies that
11 predated the TVT?

12 A. Well, the material used to
13 manufacture TVT mesh is Prolene polypropylene
14 filaments. And a great deal of work was done in the
15 mid '60s and beyond, demonstrating biocompatibility
16 of that product and essentially received FDA
17 approval.

18 Q. What is an NDA?

19 A. An NDA is a new drug application.

20 And at the time of the development of Prolene
21 suture, polypropylene sutures were considered drugs.

22 Q. And did Ethicon go through a new drug
23 application in order to have FDA approve the
24 polypropylene suture that's now used in TVT mesh?

25 MR. THORNBURGH: Objection; beyond

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1 the scope.

2 THE WITNESS: Yes.

3 BY MR. THOMAS:

4 Q. And the first five studies in your
5 degradation section are studies submitted to the FDA
6 in connection with the Prolene suture NDA, correct?

7 A. That's correct.

8 Q. And let's talk about those briefly.

9 Study of tissue reaction to the colorless and
10 pigmented monofilament polypropylene suture in the
11 rat, rabbit, and the dog.

12 Just tell me briefly what those
13 studies are.

14 A. These were tissue reaction studies in
15 three species of animals, with colored and
16 non-colored suture, looking at tissue reaction over
17 time.

18 Q. And how long were those studies?

19 A. The rat study was two years. That's
20 the lifetime of a rat.

21 The dog study was two years. And the
22 rabbit study was 90 days.

23 Q. And are those considered long-term
24 studies?

25 A. The two-year rat as a lifetime study

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1 is certainly a long-term study, as with the dog
2 study of a two-year duration.

3 Q. And what's the purpose of doing a
4 tissue reaction study to a polypropylene suture in
5 an NDA?

6 A. So for the purposes of a suture, the
7 most important thing that needs to be determined is
8 the tissue reaction of the material over time.

9 Q. And you have reviewed the tissue
10 reaction studies from the NDA?

11 A. Yes.

12 Q. And are the tissue reaction findings
13 for the polypropylene suture approved by the FDA
14 similar to the findings that you have reviewed with
15 respect to Prolene mesh?

16 MR. THORNBURGH: Objection to the use
17 of the word, approved, as well as outside the scope
18 of his designation.

19 THE WITNESS: The tissue reaction is
20 very similar.

21 BY MR. THOMAS:

22 Q. Okay. And you understand that in
23 order for Ethicon to be able to market this
24 polypropylene suture, known as Prolene suture, the
25 FDA had to approve the NDA?

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2 CERTIFICATE

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5 I HEREBY CERTIFY that the witness was
6 duly sworn by me and that the deposition is a true
7 record of the testimony given by the witness.

8

9 It was requested before completion of
10 the deposition that the witness, THOMAS A. BARBOLT,
11 Ph.D., have the opportunity to read and sign the
12 deposition transcript.

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17 MICHELLE L. GRAY, a Registered
18 Professional Reporter, Certified
19 Shorthand Reporter and Notary Public

Dated: January 16, 2014

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22 transcript does not apply to any reproduction of the
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